



Food and Drug Administration
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March 23, 2015

SeaSpine, Incorporated
Ms. Michelle Willis
Director, Regulatory Affairs
2302 La Mirada Drive
Vista, California 92081

Re: K150469
Trade/Device Name: Integra® Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: February 17, 2015
Received: February 23, 2015

Dear Ms. Willis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150469

Device Name

Integra® Laminoplasty System

Indications for Use (Describe)

The Integra Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) for laminoplasty procedures. The Integra Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Contact Details

Applicant Name: SeaSpine, Inc. (A subsidiary of Integra LifeSciences Corporation)

Address: 2302 La Mirada Drive, Vista, CA 92081

Phone number: (760) 216-5104

Fax number: (760) 727-8891

Contact person: Michelle Willis, - Director, Regulatory Affairs

Email address: michelle.willis@integralife.com

Date Prepared: February 17, 2015

2. Device Name

Trade Name: Integra® Laminoplasty System

Common Name: Laminoplasty Plating System

Classification Name: Spinal Interlaminar Fixation Orthosis (21 CFR 888.3050)

Product Code: NQW, Class II

3. Legally Marketed Predicate Device(s)

Predicate	510(k) Number	Product Code	Trade Name	Manufacturer
Primary	K130830	NQW	Integra Laminoplasty System	SeaSpine, Inc.
Reference	K091623	NQW	NuVasive (Leverage) Laminoplasty Fixation System	NuVasive, Inc.
Reference	K050082	NQW	CENTERPIECE™ Plate Fixation System	Medtronic Sofamor Danek USA, Inc.

4. Device Description

The Integra Laminoplasty System consists of titanium alloy plates and screws that are attached to the lamina after a laminoplasty procedure. Implants are available in a range of sizes and shapes, as well as in various screw hole configurations to accommodate variations in patient anatomy. The system also includes instruments to assist with implantation, and a tray for organization and storage

5. Intended Use/Indications for use

The Integra Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) after laminoplasty procedures. The Integra Laminoplasty System is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

6. Substantial Equivalence Comparison

The Integra Laminoplasty System is substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

7. Non-clinical Testing

The Integra Laminoplasty System demonstrated equivalent performance to the predicate systems through static testing per ASTM F2193.

8. Clinical Testing

No clinical testing was required to demonstrate equivalence.

9. Conclusions

The submitted data demonstrate that the Integra Laminoplasty System is as safe, as effective, and performs at least as safely and effectively as the cited legally marketed predicate devices.